

Docket No.: 4007.008

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of  
**Johannes COY**

Examiner: **Aeder, Sean E.**

Application No.: **10/511,813**

Group Art Unit: **1642**

Filed: **October 19, 2004**

Confirmation No.: **6538**

Attorney Docket No.: **4007.008**

Customer No.: **30448**

For: **COMPOSITIONS AND METHODS FOR DETECTION AND TREATMENT OF  
PROLIFERATIVE ABNORMALITIES ASSOCIATED WITH  
OVEREXPRESSION OF HUMAN TRANSKETOLASE LIKE-1 GENE**

**RESPONSE TO RESTRICTION AND SPECIES ELECTION  
REQUIREMENTS**

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is in response to the Office Action mailed June 23, 2006 having a one-month shortened statutory deadline. Applicant petitions for a four-month extension of time under 37 C.F.R. 1.136, extending the due date to November 23, 2006.

**I. Restriction Requirement**

Restriction is now required between the invention identified as those of Groups (I)-(XVI) for prosecution in the above-referenced application:

- |           |                                                                                                                                                                                                                |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Group I   | Claims 34-38, 40, and 44-50, as specifically drawn to a method for detecting the presence or absence of human transketolase like-1 polynucleotide expression.                                                  |
| Group II  | Claims 34-39, 41-43, and 50, as specifically drawn to a method for detecting the presence or absence of human transketolase like-1 polypeptide expression.                                                     |
| Group III | Claims 51-53 and 62, as specifically drawn to a human transketolase like-1 polynucleotide and a kit comprising a nucleic acid probe that specifically hybridizes to human transketolase like-1 polynucleotide. |
| Group IV  | Claims 51-53, relating to a kit comprising an antibody probe that specifically hybridizes to human transketolase like-1 polypeptide.                                                                           |
| Group V   | Claims 54-60, relating to a method of treating disorders comprising administering a human transketolase like-1 polynucleotide.                                                                                 |
| Group VI  | Claims 54-60, relating to a method of treating disorders comprising administering a human transketolase like-1 polypeptide.                                                                                    |

- |            |                                                                                                                                                  |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| Group VII  | Claims 61-62, relating to a method for identifying and obtaining a drug candidate for therapy of tumors and compounds identified by said method. |
| Group VIII | Claim 62, relating to an antithiamine compound.                                                                                                  |
| Group IX   | Claim 62, relating to an inhibitor of transketolase enzyme.                                                                                      |
| Group X    | Claim 62, relating to an inhibitor of transketolase like-1 activity.                                                                             |
| Group XII  | Claims 63-64, relating to a method for rational tumor management comprising administering antithiamine compounds.                                |
| Group XIII | Claims 63-64, relating to a method for rational tumor management comprising administering inhibitors of transketolase enzyme activity.           |
| Group XIV  | Claims 63-64, relating to a method for rational tumor management comprising administering transketolase like-1 antisense constructs.             |
| Group XV   | Claims 63-64, relating to a method for rational tumor management comprising administering ribozymes for transketolase like-1.                    |
| Group XVI  | Claims 63-64, relating to a method for rational tumor management comprising reduced administration of thiamine.                                  |

Applicant elects with traverse Group I, defined as claims 34-48, 40 and 44-50. Applicant explicitly reserves the right to pursue the remaining claims in divisional applications.

Applicant disagrees with the Examiner that the technical feature linking group I-XVI is the previously disclosed human transketolase like-1 gene. The technical feature linking groups I-XVI is instead the diagnosis of cancer by the detection of the human transketolase like-1 gene. Applicant particularly traverses with regard to the separation of Groups (I), (II), (III) and (IV), as all three sets of claims are overtly related to the diagnoses of cancer by detection of human transketolase like-1 gene or polypeptide. The division of groups based upon polynucleotide or polypeptide expression is unnecessarily restrictive, because detection of the polypeptide serves to evidence presence and expression of the gene. Further, the kits claimed in groups II and IV utilize the same methods introduced in Groups I and II. Groups I --IV demonstrate unity of invention by all relating to the special technical feature of diagnosis of cancer by the detection of the human transketolase like-1 gene. Applicant respectfully requests the withdrawal of the restriction requirement amongst Groups I-IV, or at least between Groups I and III.

## **II. Species Election Requirement**

### **A. Genus of Cancer and Tumor Type**

Applicant is also required to elect a species of cancer and tumor listed in claims 34-36. Applicant elects with traverse colon cancer and colon tumor. Applicant submits that claims 34-64 read onto the elected species of colon cancer and colon tumor.

Applicant respectfully traverses the Species Election Requirement and respectfully requests reconsideration thereof based on the following. Under PCT Rule 13.1, Applicant is entitled to prosecute a single application that relates to a group of inventions so linked as to form a single general concept. Applicant's application meets the requirements of PCT rule 13.1.

Applicant has presented an application which relates to the single general concept of a method for detection of the early stages of cancerous cells. As human transketolase like-1 is produced regardless of the type of cancer or tumor being detected, the special technical feature, detecting transketolase like-1 gene to diagnose early stages of cancer, would be useful whether one were testing for colon, gastric, or lung tumors or cancer. In contrast, it appears that the Examiner has taken the position that this general concept can be dissected as unrelated species. Applicant respectfully disagrees. The single general concept does not depend on whether colon, lung, or gastric cancer or tumor is being detected, as any of these three types of cancer can be diagnosed according to the claimed subject matter based upon the single general concept of detection of transketolase like-1 gene or protein.

Accordingly, Applicant respectfully requests the withdrawal of the Species Election Requirement, as applied to an election of colon cancer and colon tumor, lung cancer and lung tumor, gastric cancer and gastric tumor.

#### **B. Genus of Sample Type**

Applicant is also required to elect a species of sample amongst: serum, urine, semen, stool, bile, or a specific cell or specific tissue sample. Applicant elects with traverse the species of specific cell or specific tissue sample. Applicant submits that claims 34-53, 61-63 read onto

the elected species of specific cell or specific tissue sample. Applicant notes that claim 37 is included in the claims reading onto the elected species because a specific cell or tissue type may comprise, for example, a biopsy.

Applicant has presented an application which relates to the single general concept of a method for detection of the early stages of cancerous cells. Human transketolase like-1 gene or protein is produced and detected according to the disclosed subject matter's unifying special technical feature regardless of the sample, or container, used to bring the transketolase like-1 to the technician's laboratory bench. Human transketolase like-1 gene or protein can be detected using the same methods whether the gene or protein is present in whole or lysed cells, cell debris, a body fluid, a tissue-sample, etc. The type of sample in no way affects the application of the special technical feature of testing for transketolase like-1 gene or protein. Accordingly, Applicant respectfully requests the withdrawal of the Species Election Requirement, as applied to an election of sample types.

### **III. CONCLUSION**

It is believed that the above represents a complete response to the Official Action and reconsideration is now in order.

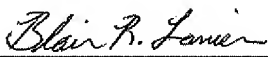
To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 50-0951 and please credit any excess fees to such deposit account.

U.S. Application No.: 10/511,813  
Response to June 23, 2006 Restriction Requirement

Attorney Docket: 4007.008

Respectfully submitted,  
AKERMAN SENTERFITT

Date: November 22, 2006

  
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